34 Robbins Street
Acton, Massachusetts 01720
27 May 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

9388 '99 JUN -2 P12:50

Re: DOCKET No. 98N-1265

To the FDA,
I am writing this letter to register my disapproval of the Memorandum of Understanding (MOU) as published by the FDA on January 21, 1999 and the Compounding Section 503A of the Modernization Act. These changes must be amended to allow pharmacist-compounded drugs, generated in a state other than the patient, to be prescribed by physicians.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, will prohibit me from obtaining my current medication from Women's International Pharmacy, a mail order prescription house, located in a state other than my own. This medication is a custom mixed natural hormone replacement drug as prescribed by my Gynecologist and is required by me because of the side effects that I incur when taking the traditional drug-company produced synthetic hormones. If this MOU passes, I will again be faced with the choice of either incurring these unpleasant and unhealthy side effects, or doing without hormone replacement therapy with its know effects on my heart, bones, and now-suspected mental capacity. As a soon-to-be-60 year old women, I have many years remaining, and the options are to live it as a productive healthy female or as an unhealthy drain on Medicare in my later years. I think the choice is obvious.

In its present form, the MOU and the Compounding Section 503A of the Modernization Act, severely restricts the rights of physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of the compounding pharmacists to serve the public's medical needs, and does so to the benefit of the large drug companies who already have much too much control on the price and distribution of their drugs. As a health consumer, I should incur no restrictions on where or from whom I purchase my medication regardless of whether the source resides in my state or some other state within the USA. Such restrictions on interstate commerce have no justification in the area in which the FDA is supposed to function, namely as the watchdog of consumer safety.

This is not a safety issue, and the FDA has overstepped its bounds with these changes. The FDA must be accountable to the people and the MOU must be amended.

Sincerely yours,

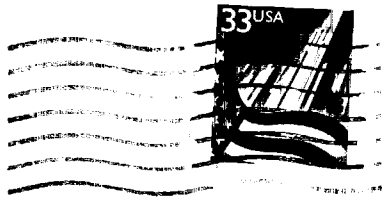
98N-1265

Dorothy A. Campbell

CC: Rep. M. Meehan Sen. E. Kennedy Sen. J. Kerry

C 3096

Dorothy A. Campbell
34 Robbins St
Acton MA 01720-2718



Dockets Branch (HFA-305
Food and Drug Admin
5630 Fishers Lane Room 1061
Rockville, MD 20857-0003

20857+0003